THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA *ex rel.* LAYNE FOOTE *et al.*, *Plaintiffs,* v. ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP, *Defendants.*	C.A. No. 1:10-cv-00095 (SLR)

PLAINTIFFS-RELATORS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT PURSUANT TO RULES 8, 9, 12(b)(1) & (6)

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NATURE AND STAGE OF THE PROCEEDINGS

Relator Layne Foote filed this *qui tam* lawsuit against his former employer, AstraZeneca LP and AstraZeneca Pharmaceuticals LP (together, "AZ"), based on his actual knowledge of AZ's use of false and misleading statements and kickbacks to induce physicians to prescribe Crestor (rosuvastatin calcium), which caused claims for payment of those prescriptions to be submitted for payment by the United States and the States. [D.I. 1] He amended his complaint to join complementary allegations of another former AZ employee, Mark T. Lorden, who observed similar corporate misconduct in a different region of the United States. [D.I. 7]

The case was filed under seal, and it remained under seal (by request of the United States) until October 31, 2013. [D.I. 1 & 50] AZ filed its initial response on January 5, 2015 [D.I. 63], and Relators responded by filing their Third Amended Complaint (TAC) on March 5, 2015.[1] [D.I. 68] AZ then filed this Motion to Dismiss [D.I. 71], arguing primarily that the TAC lacks sufficient detail, that its allegations are consistent with lawful explanations for AZ's actions, and that Relator Lorden's claims are precluded as a matter of law. To reach those conclusions, however, AZ ignores the plain language of the relevant statute and the TAC itself, which provides a detailed and comprehensive description of the manner and method by which the company used false and misleading statements and kickbacks to induce physicians to prescribe Crestor and cause false claims for reimbursement to be paid by government programs.

The Relators' claims are not based on supposition or conjecture, nor do they seek to penalize truthful speech. Instead, the TAC provides a precise description of the "who, what, when, where, why, and how" of AZ's misconduct, more than satisfying the pleading standard

[1] The complaint had been amended twice while it was under seal. [D.I. 7 & 19]

recently articulated by the Third Circuit in *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014). Accordingly, the motion to dismiss must be denied.

SUMMARY OF ARGUMENT

AZ argues the TAC should be dismissed because it seeks to punish mere off-label (*i.e.*, not FDA-approved) promotion, because the patient populations for approved and unapproved uses of Crestor "overlap entirely," and because the unapproved uses for which it promoted Crestor are "medically accepted." Mem. 13. This mischaracterization of the TAC's allegations is not a basis for dismissal at this early stage. More importantly, though, the Court should reject this straw man because the TAC does not allege that AZ is liable simply because it promoted Crestor for uses not approved by the FDA. Instead, the TAC alleges that AZ is liable under the federal False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*., and state analogues because it used *false and misleading statements* to promote Crestor.

The TAC explains how AZ implemented a scheme to steal market share from its established competitors by (1) using false and misleading statements to persuade physicians that Crestor is superior to other statins (TAC ¶¶ 172-223, 253-77); (2) using false and misleading statements to target physicians who treat minority ethnic populations (*id*. ¶¶ 224-52); (3) using false and misleading statements to induce prescriptions of Crestor for unproven and as-yet unapproved uses (*id.* ¶¶ 283-393); and (4) providing kickbacks to induce physicians to prescribe Crestor (*id.* ¶¶ 435-511). Whether the unapproved uses that AZ pushed on physicians overlap with approved uses and patient populations is irrelevant, because the salient allegation is that AZ used *false and misleading* statements about those uses to promote Crestor, conduct which is actionable *irrespective* of the drug's FDA approval profile.

Nor is the TAC too vague. To the contrary, it is unusually detailed, plainly putting AZ on notice of the manner and means by which it is alleged to have violated the law in its promotion of Crestor. The TAC identifies by name particular AZ supervisors who directed the scheme, particular front-line employees who were required to implement the scheme, and particular physicians who treated government program beneficiaries and helped to implement the fraud. It also outlines AZ's illegal payment of kickbacks in the form of speaker fees and other monies to induce prescriptions and government program payments. The allegations are precise – *including dates, locations, verbatim scripts, and internal AZ emails describing the fraud* – and they explain in detail how AZ's misrepresentations and kickbacks induced physicians to prescribe Crestor and cause claims for reimbursement to be submitted. In view of the Third Circuit's decision in *Foglia*, AZ's claim that the TAC does not allege liability with sufficient specificity falls flat.

AZ's remaining arguments also lack merit. Its argument based on the statute of limitations rings hollow because Relators' claims plainly relate back to the Second Amended Complaint (SAC), and AZ's argument to dismiss certain state claims fails because it is premature or legally deficient. Likewise, the first-to-file rule does not bar Relator Lorden's claims because (1) his claims were not filed in a separate action or through intervention, and (2) the earlier-filed *De Souza* action was no longer pending when Lorden and Foote filed their TAC. Finally, if any claims are dismissed, such dismissal should be without prejudice, and with leave to amend.

STATEMENT OF FACTS

Crestor is a prescription drug manufactured, marketed, and sold by AZ. It is a member of the class of drugs known as "statins," which generally are prescribed to lower cholesterol levels in the blood. TAC ¶ 122. When Crestor finally received limited marketing approval from the FDA in 2003, it was late to a mature and highly competitive market. *Id*. ¶ 126. Its competitor

drugs were well-regarded by physicians (who had years of experience prescribing them), and they did not share Crestor's ominous safety profile (which had been well-publicized prior to its launch). *Id*. ¶¶ 126-32. Moreover, Crestor's chief competitors – Lipitor and Zocor – were approved for a wider array of uses, providing another obstacle to success. *Id*. ¶¶ 140-47.

Undaunted by the competition or Crestor's limited regulatory approval, AZ implemented a nationwide scheme to capture and expand sales by misleading physicians and government programs regarding Crestor's safety and efficacy. The centerpiece of the scheme was a marketing plan characterized by false and misleading statements to physicians and government programs, urging them to prescribe and reimburse Crestor because it was superior to other statins (branded and generic) for all patients, and particularly for certain ethnic groups, regardless of diagnosis. *See* TAC ¶¶ 172-277. The TAC provides a detailed description of the manner and means by which AZ promoted these false and misleading statements, it describes the statements themselves, and it identifies specific physicians and government programs who were misled by them to prescribe and reimburse Crestor as a result. *Id*.

The TAC also explains how AZ used false and misleading statements to induce physicians to prescribe Crestor for unproven uses, including regression of atherosclerosis and prevention of an array of cardiac and non-cardiac conditions. *See* TAC ¶¶ 283-335 (regression), ¶¶ 336-97 (prevention of heart attacks and strokes), ¶¶ 398-434 (other uses). Again, the TAC provides a detailed description of the manner and means by which AZ directed the promotion of these false and misleading statements, it describes the statements themselves, and it identifies specific physicians and government programs who were misled by them to prescribe and reimburse Crestor, respectively, as a result. *Id*.

REGULATORY BACKGROUND

I. The Food, Drug, and Cosmetic Act

To protect public health and safety, the FDA regulates the manufacture and marketing of prescription medications. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, drug manufacturers are prohibited from promoting their drugs for uses not specifically approved by the FDA, *i.e.* "off-label" uses. *See* TAC ¶ 59. The FDCA also prohibits manufacturers from promoting a drug as "safer than it has been demonstrated to be by substantial evidence," 21 C.F.R. § 202.1(e)(6)(iv), or through unsubstantiated claims that the drug is safer or more efficacious than competitors' drugs, 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). *Id.* ¶ 63. Such promotion constitutes illegal misbranding under the FDCA. 21 U.S.C. §§ 331, 352.[2]

II. Prescription Drug Reimbursement under Government Programs

Under Medicaid and Medicare (together, "Government Programs"), a prescription is reimbursable only if used for a "medically accepted indication." *See* 42 U.S.C. §§ 1395w-102(e)(1)(A), 1396b(i)(10), 1396r-8(k)(2)-(3). A use is a "medically accepted indication" if it is approved by the FDA or supported by one of the statutory drug compendia. *Id*. § 1396r-8(k)(6) (Medicaid); *id*. § 1395w-102(e)(4) (Medicare); *see id.* § 1396r-8(g)(1)(B)(i) (listing compendia).

[2] Although AZ notes that physicians are permitted to prescribe approved drugs for unapproved uses (Mem. 4), the salient point is that AZ may not *promote* its drugs for unapproved uses. That prohibition is rooted in the FDCA's proscription against the introduction or delivery for introduction into interstate commerce of a "new drug" (*i.e.*, one that is not generally recognized as "safe and effective" for its intended use) that has not been approved by the FDA. *See* 21 U.S.C. §§ 321(p), 331(d) & 355(a). A new intended use renders an approved drug a "new drug" with respect to that new use. *Id.* As referenced, the prohibition on manufacturers promoting approved drugs for unapproved uses also can be found in the FDCA's misbranding provisions. *See also* S. Rep. No. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2901-2903 (statement of Senators Kefauver *et al*. explaining reasons for changes to "new drug" definition).

Drugs prescribed for uses neither approved by the FDA, nor supported by the compendia are not for medically accepted indications and, thus, are not reimbursable.[3]

The relevant statutory and regulatory background is described in further detail in the TAC. *See* TAC ¶¶ 42-83 (FDA statutory and regulatory system); *id*. ¶¶ 84-119, 515-16 (government healthcare programs). The TAC also explains why and how AZ's violation of these laws caused the submission of false claims actionable under the FCA. *See, e.g., id.* ¶¶ 172-282 (fraudulent superiority claims to induce prescriptions and false claims), ¶¶ 283-434 (false and misleading off-label promotion to induce false claims), ¶¶ 435-511 (payment of kickbacks to induce prescriptions and false claims), ¶¶ 515-42 (process by which false claims were submitted under Medicaid and Medicare).

III. Crestor's Limited Medically Accepted Uses

Crestor's initial FDA approval in 2003 was narrowly limited to lowering "bad" cholesterol and raising "good" cholesterol in only three contexts. *See* TAC ¶ 141 (describing boundaries of initial approval). Four years later, in November 2007, it was approved "as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels." *Id*. ¶ 142. And in February 2010, Crestor received expanded approval for "primary prevention of cardiovascular disease" in a narrow band of patients. *Id*. ¶ 143. To this day, Crestor's FDA approvals remain more limited than those of its competitors. *Id*. ¶¶ 140-47.

[3] AZ suggests that its promotion of Crestor is commercial speech, shielded from scrutiny by the First Amendment. Mem. 4-5. But the First Amendment only protects commercial speech that is truthful; it does not protect *fraudulent* speech. *See New York Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964); *see also United States v. Alvarez*, 132 S. Ct. 2537, 2544 (2012). Thus, "off-label promotion [by a drug manufacturer] that is false or misleading is not entitled to First Amendment protection." *United States v. Caronia*, 703 F.3d 149, 165 n.10 (2d Cir. 2012). The same is true of false or misleading promotion of approved uses.

The TAC alleges that AZ used false and misleading statements about its ASTEROID trial to induce the use and reimbursement of Crestor as a stand-alone therapy to *regress* atherosclerosis, and it explains that such use was not reimbursable by Government Programs because it was neither approved by the FDA, nor recommended by the statutory compendia. *See* TAC ¶¶ 288-319. AZ disputes this, asserting that regression is not an independent therapeutic use that requires FDA approval or compendia support to be reimbursed, but is, instead, "simply a result of the treatment for general atherosclerosis and cardiovascular disorders," which are supported by the compendia and thus reimbursable by Government Programs. Mem. 7. According to AZ, use of Crestor to regress atherosclerosis is subsumed within the DrugDex compendium's support of Crestor for "Generalized Atherosclerosis." *Id*. at 16. Whether Crestor has adequate compendia support to be reimbursable by Government Programs, however, is a disputed question of fact that is not ripe for review. *See* discussion *infra* pp. 19-21.

ARGUMENT

In deciding a motion to dismiss under Rule 12(b)(6), the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). To survive a motion to dismiss, the factual allegations need only "raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true." *Bell Atlantic Corp. v. Twombley*, 550 U.S. 544, 555 (2007); *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 (3d Cir. 2010) (the complaint need only "allege enough fact[s] to state a claim to relief that is

plausible on its face") (internal quotations omitted). The "defendant bears the burden of showing no claim has been stated." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000).

This standard "does not impose a probability requirement" and it does not require a plaintiff to "plead facts supporting an inference of defendant's liability more compelling than the opposing inference." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 341 n.42 (internal quotation omitted). Instead, the plaintiff must plead only "factual content to allow the court to draw a reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (internal citations omitted). The TAC satisfies this requirement.

I. Relators Allege with Plausibility and Particularity that AZ Used Statements to Induce Prescriptions and Cause False Claims to be Submitted and Paid

The FCA provides liability for "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). *See also United States ex rel. Wilkins v. United Health Group., Inc.*, 659 F.3d 295, 311-12 (3d Cir. 2011) (plaintiff must plead "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent") (internal quotation omitted). It also proscribes the creation of false records in order to avoid an obligation to make payment to the federal government or a state government. 31 U.S.C. § 3729(a)(1)(G). State false claims act laws generally are construed consistently with the federal act. *See, e.g., United States ex rel. Washington v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 458 (W.D. Pa. 2012).

A. The TAC Satisfies Minimum Pleading Requirements

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "FCA claims must be pleaded with particularity in accordance with [Rule] 9(b)." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004). The standard is flexible, however, and Rule 9(b) "must be read in conjunction with the liberal pleading rule of Fed. R. Civ. P. 8(a) which requires only that the complaint set forth 'a short and plain statement of the claim.'" *See Knight v. Rourke*, No. 93-5841, 1995 U.S. Dist. LEXIS 2919, at *10 (E.D. Pa. Mar. 8, 1995); *see also United States ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00-CV-4863, 2003 U.S. Dist. LEXIS 27469, at *10 (E.D. Pa. Aug. 14, 2003) (same).

The Third Circuit recently rejected the notion that an FCA plaintiff must show "representative samples of the alleged fraudulent conduct" or "specify the time, place, and content of the acts and the identity of the actors." *Foglia*, 754 F.3d at 155. Instead, the Court of Appeals held "it is sufficient for a plaintiff to allege particular details of a *scheme* to submit false claims paired with *reliable indicia* that lead to a strong *inference* that claims were actually submitted." *Id*. (quotations omitted, emphasis added). The Court of Appeals noted this is consistent with the approach taken by the First, Fifth, and Ninth Circuits, which "do[] not require that the exact content of the false claims in question be shown." *Id*. at 156. It also is consistent with the purpose of Rule 9(b), which is to provide adequate notice to the defendant. *Id*. (adopting a more lenient pleading requirement under Rule 9(b) in false claims actions because the touchstone is fair notice). *And just yesterday*, the D.C. Circuit expressly adopted the rule enunciated in *Foglia*, holding that "the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint, especially

not when the relator alleges that the defendant knowingly caused a third party to submit a false claim as part of a federal regulatory program." *United States ex rel. Heath v. AT&T, Inc.*, No. 14-7094, 2015 U.S. App. LEXIS 10547, at *23-24 (D.C. Cir. June 23, 2015).

Rule 9(b)'s particularity requirement is relaxed further still when (as here) the defendant has significant control over the factual circumstances; thus, a plaintiff is not required to plead information that is, by its nature, wholly within a defendant's control. *See In re Rockefeller Center Prop., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) ("courts should be sensitive to situations in which sophisticated defrauders may successfully conceal the details of their fraud . . . where it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control, the rigid requirements of 9(b) may be relaxed") (internal quotations omitted); *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton*, No. 08-1265, 2009 U.S. Dist. LEXIS 38898, at *15 (D.N.J. May 6, 2009) (same). Thus, a relator need only allege "[s]ufficient facts to establish 'a plausible ground for relief.'" *Foglia*, 754 F.3d at 158 (citing *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009)).

Following *Foglia*, courts within this Circuit have consistently denied motions to dismiss predicated on Rule 9(b) in FCA cases pleading facts substantially similar to those pled here.[4] Even before *Foglia*, these courts applied the nuanced pleading standard adopted in *Foglia*.[5]

[4] *See United States ex rel. Nevyas v. Allergan, Inc.*, No. 2:09-cv-00432-MAK, 2015 WL 3429381, at *1 (E.D. Pa. May 26, 2015); *United States ex rel. Cestra v. Cephalon, Inc.*, No. 2:14-cv-01842, 2014 WL 3498761 (E.D. Pa. June 3, 2015); *United States ex rel. Silver v. Omnicare, Inc.*, No. 11-1326, 2014 U.S. Dist. LEXIS 136800, at *9-15 (D.N.J. Sept. 29, 2014); *United States ex rel. Greenfield v. Medco Health Sys., Inc.*, No. 12-522 NLH AMD, 2014 U.S. Dist. LEXIS 135767, at *29-30 (D.N.J. Sept. 26, 2014); *United States ex rel. Ryan v. Endo Pharms., Inc.*, 27 F. Supp. 3d 615, 623-25 (E.D. Pa. 2014); *see also United States ex rel. Richards v. R&T Invs. LLC*, 29 F. Supp. 3d 553, 563-64 (W.D. Pa. 2014).

[5] *See*, *e.g.*, *United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 373 (E.D. Pa. 2014); *United States ex rel. Galmines v. Novartis Pharms. Corp.*, No. 06-3213, 2013 U.S. Dist.

Consistent with *Foglia* and its progeny, AZ's motion to dismiss should be denied because the TAC alleges with particularity the "who, what, when, where and how of the events at issue." *In re Rockefeller Center*, 311 F.3d at 217 (internal citations omitted) (discussing pleading standard under Rule 9(b)). And the TAC makes plain that liability is founded not simply on off-label promotion, but, instead, on the use of false and misleading statements in support of off-label promotion, and that those false and misleading statements caused false claims to be submitted and paid. *See*, *e.g.*, *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 52 (D. Mass. 2001) ("the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government. . . ."); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 890 (N.D. Cal. 2009) (same); *United States v. Genentech, Inc.*, No. 11-3691, 2014 U.S. Dist. LEXIS 175223, *8-9 (D.N.J. Dec. 18, 2014) (same).[6]

1. The TAC Leads to a Strong Inference that AZ's False and Misleading Superiority Pitch Caused False Claims to be Submitted and Paid

AZ contends "it is almost inconceivable" that its superiority claims induced prescriptions for non-reimbursable uses. Mem. 13-14. What AZ fails to consider, much less counter, however, are well-pleaded allegations that those claims were false and misleading.

LEXIS 83100, at *36-37 (E.D. Pa. June 13, 2013) (citing *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 680 (E.D. Pa. 2010)).

[6] AZ contends that "allegations of off-label promotion alone are not sufficient to establish a violation of the FCA." Mem. 11. The contention is irrelevant here because the TAC alleges with specificity that AZ accomplished its fraud through false and misleading conduct (*e.g.*, using false and misleading statements to cause false claims to be submitted), which does establish an FCA violation. *See* discussion *infra*; *see*, *e.g.*, *Franklin*, 147 F. Supp. 2d at 52 ("the alleged FCA violation arises – not from unlawful off-label marketing activity itself – but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct").

a. The TAC Alleges AZ's Superiority Claims Were False and Misleading

The fundamental flaw in AZ's argument is that the TAC does not (as the Motion presupposes) assign liability based simply on the promotion of superiority claims that were not approved by the FDA. Rather, the TAC assigns liability based on AZ's promotion of *false and misleading* superiority claims. *See* TAC ¶¶ 172-282. For example:

- The TAC explains how AZ used its STELLAR trial to advance superiority claims that were false and misleading. *See* TAC ¶¶ 174-76 (noting FDA's demand that the company cease dissemination of STELLAR promotional materials that presented a "misleading comparison" of Crestor with other statins), ¶ 189 (AZ trained sales personnel to misleadingly promote Crestor as better tolerated than Lipitor, despite a lack of adequate clinical support).
- The TAC describes particular instructions, emails, and role-playing exercises by which AZ managers directed sales personnel to advance false and misleading superiority claims when promoting Crestor to physicians. *See*, *e.g.,* TAC ¶¶ 161, 201 (role-playing to promote superiority), ¶ 187 (District Sales Manager Cynthia Burrell), ¶¶ 190 & 254-55 (DSM Chris Dufault), ¶¶ 191-95, 259-61, 266-72 & 274-75 (DSM Jack Hodge), ¶ 258 (DSM Chris Czech), ¶ 273 (Regional Sales Director Parker Fretwell).
- The TAC explains how AZ made misleading superiority claims to Government Programs to induce them to reimburse prescriptions for Crestor. *See* TAC ¶¶ 197-219; *see also id.* ¶¶ 210, 215, 217, 221-23, 249-52, 347 (describing particular misrepresentations to particular states' Medicaid programs). And it explains how AZ then used Crestor's wrongly obtained reimbursement status to support its bogus superiority claims. *See id.* ¶¶ 221-23.

- The TAC explains how AZ deliberately misled physicians and government programs into believing that Crestor is the most effective statin for the treatment of African-American, Hispanic, and South Asian patients. *See* TAC ¶¶ 224-52.
- The TAC explains how AZ misled physicians through false and misleading statements that Crestor is superior to generic statins. *See* TAC ¶¶ 253-77. It even describes verbatim messages that AZ personnel were instructed to use to advance this claim. *Id*. ¶¶ 266-77.

Plainly, the TAC alleges not simply that AZ advanced an unapproved superiority message, but that it advanced a false and misleading, unapproved superiority message. And where AZ's false and misleading superiority claims caused physicians to prescribe Crestor – whether for FDA-approved or unapproved uses – claims for reimbursement of such uses were false within the meaning of the FCA and state analogues. *See*, *e.g.*, *United States ex rel. Hutchenson v. Blackstone Medical, Inc.*, 647 F.3d 377, 384 (1st Cir. 2011) (holding that claims can be false or fraudulent, even if not false on their face, if they were submitted due to misrepresentations or other wrongful conduct); *cf. United States. v. Universal Health Serv., Inc.*, 780 F.3d 504, 511 (1st Cir. 2015) (finding that in determining "falsity," "[w]e simply ask whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of a payment") (citing *New York v. Amgen, Inc.*, 652 F.3d 103, 110 (1st Cir. 2011)).

b. The TAC Alleges With Plausibility and Particularity That AZ's False and Misleading Superiority Claims Caused False Claims to be Paid

Side-stepping allegations that its superiority claims were false and misleading, AZ argues that one cannot infer from the TAC that its superiority pitch caused false claims to be submitted. Mem. 13. This argument strains credulity, for it simply ignores the averments of the TAC.

The TAC does not allege only that AZ's superiority claims were false and misleading; rather, it also identifies *specific* Government Programs whose reimbursement policies were affected by the misleading superiority promotion, and it identifies *particular* health care providers who treated Government Program beneficiaries *and* who prescribed Crestor as a result of those bogus superiority claims. *See, e.g.,* TAC ¶¶ 215, 217-18 (Government Programs), ¶¶ 184-85 (Drs. Bechara, O'Leary, Asher)[7], ¶ 190 (Dr. Bhat), ¶ 223 (Drs. Yu, Sahay, Joshi, Rio), ¶¶ 240-42 (Drs. Yuil, Rao, Danesh, Polo, and NPs Touch & Viel), ¶ 258 (Drs. Brown, Gustafson, Bhat), ¶¶ 263-64 (Drs. Islam, Hart, Sauls, and NP Kulesza), ¶ 277 (Dr. Lalude). For example, the TAC explains that Dr. Rashidul Islam (New Salisbury, Indiana) suddenly increased his Crestor utilization to more than 80 percent of his total statin prescriptions upon receiving AZ's false and misleading superiority pitch. TAC ¶ 263. And, confirming that AZ's specific intent was to induce the Government Program reimbursements, the TAC also describes the process by which AZ coupled its misleading superiority promotion with instructions to health care professionals on how to prescribe Crestor in a way that would avoid formulary restrictions that preferred generic statins. *Id*. ¶¶ 256-58. These allegations certainly represent the requisite *reliable indicia* that lead to a strong *inference* that claims actually were submitted. *See Foglia*, 754 F.3d at 156. AZ has made no attempt to neutralize these strong inferences, nor could it successfully do so at this stage.

[7] AZ singles out allegations regarding Dr. Bechara as being representative and inadequate because the TAC does not allege that he prescribed Crestor for non-reimbursable uses. Mem. 14. But that ignores the specific allegation that "Relator Lorden was trained and instructed by [AZ] to make [its] deceptive STELLAR superiority promotion" to Dr. Bechara (and others), that he did so, and that it was the "false and misleading representations" that caused Dr. Bechara (and others) to prescribe Crestor, and that caused false claims to be submitted and paid. TAC ¶ 184 (emphasis added). Whether approved by the FDA or not, claims that were induced by false and misleading representations are false within the meaning of the FDA and state analogues.

The TAC contains these details, and many more. Though it does not identify specific false claims that were submitted for reimbursement (that information is solely within AZ's custody and control), such detail is *not* required to survive a motion to dismiss; instead, a complaint need only provide reliable indicia that lead to a strong inference that false claims were submitted. *See Foglia*, 754 F.3d at 156. Though unaddressed by AZ, the TAC sufficiently describes AZ's scheme to submit false claims by identifying (1) particular false and misleading instructions by AZ managers, (2) particular false and misleading superiority claims made to physicians and Government Programs, and (3) particular physicians who treated Government Program beneficiaries and whose prescribing activity actually increased upon receiving the false and misleading superiority claims. Thus, the TAC does not simply allege facts that are "consistent" with liability. *Cf.* Mem. 3. Rather, it provides an ample factual basis upon which to infer that AZ's false and misleading promotion of Crestor as being superior to other statins actually induced physicians to prescribe Crestor, and that it likewise caused claims for reimbursement to be submitted to, and paid by, Government Programs. *See Foglia*, 754 F.3d at 156; *cf. Silver*, 2014 U.S. Dist. LEXIS 136800, at *9 (applying *Foglia*, and denying motion to dismiss); *Medco Health Sys.*, 2014 U.S. Dist. LEXIS 135767, at *29) (same). AZ cannot credibly argue it lacks notice of Relators' claims, or that more is necessary at this stage.

2. Relators' Allegations Lead to a Strong Inference that AZ's False and Misleading Regression and Primary Prevention Claims Caused False Claims to be Submitted and Paid

AZ's summary argument that Relators have not stated plausible claims based on the promotion of Crestor to regress atherosclerosis and prevent heart attacks and strokes is similarly flawed. The gist of the defense is that (1) the TAC does not allege a factual basis upon which to infer that physicians wrote prescriptions for non-reimbursable uses, and (2) even if it did,

prescriptions to regress atherosclerosis and reduce the risk of heart attacks and strokes are reimbursable. Mem. 15-16. AZ is wrong for three reasons.

First, the suggestion that the TAC does not allege a plausible basis for liability ignores the law and the allegations of the TAC itself. AZ simply is not correct when it argues the TAC "stops short" of alleging that Crestor prescriptions were written to regress atherosclerosis or prevent heart attacks and strokes, and that associated claims for reimbursement were submitted. Mem. 15. Instead, the TAC alleges in detail how AZ caused both to occur. For example:

- The TAC explains how AZ made its deceptive regression pitch to multiple physicians, inducing them to prescribe Crestor and causing Government Programs to reimburse associated claims. *See* TAC ¶ 300 (Dr. Feitelson), ¶ 307 (Dr. Anggelis), ¶ 308 (Drs. Nabbout, Bechara, O'Leary).
- The TAC explains how AZ promoted its misleading regression pitch to Drs. Kemparajurs, Cecil, Bhakta, and Donovan, which induced them to prescribe Crestor. TAC ¶ 303.
- The TAC explains how AZ deployed a five-week sales blitz in March 2006 to promote its misleading regression message (TAC ¶¶ 310-14), and how that induced specific physicians to prescribe Crestor and caused Government Programs to reimburse associated claims. *See* TAC ¶ 311 (Dr. Allen), ¶ 313 (Dr. Kelly).
- The TAC explains how AZ targeted specific Government Programs for its false and misleading regression promotion, and how it succeeded in securing favorable reimbursement status. *See* TAC ¶ 316 (misrepresentations to Alaska State Medicaid Program), ¶ 317 (misrepresentations to Passport Health Plan, which is a Medicaid managed plan).
- The TAC explains how AZ used its METEOR study misleadingly to reinforce its false regression message (*see* TAC ¶¶ 320-35) in discussions with particular health care providers

and Government Programs, inducing physicians to prescribe Crestor and causing Government Programs to reimburse associated claims. *See* TAC ¶ 329 (Dr. Bhat), ¶ 331 (Dr. Bosler), ¶ 332 (Drs. Nguyen, Lo, Savage), ¶¶ 334-35 (Washington State Medicaid Program).

- The TAC explains how AZ made its deceptive prevention pitch to particular physicians, inducing them to prescribe Crestor and causing Government Programs to reimburse related claims. *See* TAC ¶ 345 (Drs. Marino, Waters, Babineau), ¶ 387 (Dr. Fowler and NPs Belcher, Stephens), ¶ 388 (Drs. Anggelis, Fineman), ¶ 389 (Drs. Nahra, Morrel, Chang).
- The TAC explains how AZ targeted specific Government Programs for its false and misleading prevention pitch, and how it succeeded in securing favorable reimbursement status. *See* TAC ¶¶ 346-48, 392-93 (Idaho and Nevada Medicaid Programs, and Welborn Health Plans – which offered several Medicare managed care plans).

The detailed allegations in the TAC, including names and details of specific false and misleading promotions, provide ample and reliable indicia supporting a strong inference that false claims were submitted as a result of those promotions. *Cf. Foglia*, 754 F.3d at 156.

Second, AZ's contention that regression claims should be dismissed because regression is not a stand-alone therapeutic use, but is instead "subsumed" within the DrugDex compendium's support of Crestor for "Generalized Atherosclerosis" (Mem. 16), is both premature and incorrect.[8] It is premature because ascertaining the extent of compendium support is a question of fact not ripe for review on a motion to dismiss. *See* discussion *infra* pp. 19-21. It is flawed because it ignores well-pleaded allegations that AZ *did* promote regression as a stand-alone

[8] AZ's Motion does not address a myriad of other allegations of false and misleading off-label promotion that also specify the who, what, when, where and why of AZ's fraud, likely because AZ must concede they are sufficiently specific and state claims for relief. *See*, *e.g.*, TAC ¶¶ 224-52 (targeting of ethnic populations), ¶¶ 253-82 (promotion against generic statins).

therapeutic use, *see* TAC ¶¶ 288-319, and because it glosses over the substance of the DrugDex reference for "Generalized Atherosclerosis," which plainly does *not* incorporate regression.[9]

Third, the suggestion that the TAC must be dismissed because regression and the prevention of heart attacks and strokes are reimbursable uses of Crestor ignores a critical building block of the TAC: the allegation that AZ induced those uses (and resulting claims for reimbursement) through false and misleading statements. *See*, *e.g.*, TAC ¶¶ 290-96, 324 (promotion of Crestor to regress atherosclerosis was knowingly false and misleading), ¶¶ 342-44, 354-63, 372-73 (promotion of Crestor to prevent heart attacks and strokes based on CORONA and JUPITER was knowingly false and misleading), ¶¶ 394-97 (AZ's *admission* that its promotion of JUPITER trial data was false and misleading); *cf. id*. ¶ 324 (AZ's promotion of the METEOR trial was knowingly false and misleading), ¶¶ 364-71 (inevitable bias in the JUPITER trial and concerns surrounding its premature termination).

AZ used false and misleading statements to induce prescriptions, rendering resulting claims for reimbursement (which it also caused) to be false within the meaning of the FCA and state analogues. AZ ignores allegations that such promotion was false and misleading, dooming its Motion because a claim induced through deception is not reimbursable. *See* discussion *supra.*

[9] The DrugDex entry for "Generalized atherosclerosis" (Section 4.5.A.10) notes "FDA Approval." Thus, it cannot be read to support use for regression because the trial routinely cited by AZ to support such use – ASTEROID – was *not* relied upon to obtain any FDA approval. Instead, the entry appears to be a reference to the METEOR trial, which was the basis for Crestor's 2007 "slow the progression" FDA approval, but which *did not* support the regression hypothesis. *See* TAC ¶¶ 42-51, 142, 289-95, 321-22.

3. Relators' Allegations Lead to a Strong Inference that AZ's False and Misleading Promotion of Crestor for Prevention of Diabetes, for Renal Protection, for Reduction of Proteinuria, and for "Pleiotropic" Effects Caused False Claims to be Submitted and Paid

AZ argues in a single paragraph that allegations it induced false claims for reimbursement of Crestor to prevent diabetes, to reduce proteinuria, and for "pleiotropic" effects must be dismissed because they are "conclusory" and "fail to establish a 'strong inference' that claims were submitted for non-reimbursable uses." Mem. 17. Once again, however, AZ ignores allegations that explain how it misled physicians into prescribing Crestor for such uses, and why such promotion was false and misleading. The TAC explains in detail exactly how AZ implemented this component of its scheme. For example:

- The TAC explains how Relator Foote was instructed to, and did, induce Drs. Cyrus, Womack and Hilb to prescribe Crestor for pre-diabetic patients because of its supposed (*i.e.*, speculative) "cardioprotective" properties. *See* TAC ¶¶ 400-01.
- The TAC explains how AZ used speaker programs (even including slides from two 2004 programs) to mislead physicians based on "data on file" into believing that Crestor had renal protective properties or even "tended to improve" renal function. *See* TAC ¶¶ 411-12.
- The TAC explains how AZ required sales personnel to use "Walking PIRs" to misleadingly promote Crestor's supposed "pleiotropic" benefits for kidney function. *See* TAC ¶¶ 413-19. AZ focused this effort on nephrologists, including Drs. Goldstein, Lee, and Pengvanich of Louisville, Kentucky. *Id*. ¶ 421.
- The TAC explains how AZ used paid speaker Dr. James Liao to promote its misleading "pleiotropic" benefits message, and how DSM Cynthia Burrell required sales staff to promote Dr. Liao's message misleadingly to dispel safety concerns and promote Crestor

for an array of unproven uses, including treatment of dementia, protection against Alzheimer's disease, and reducing the risk of depression. *See* TAC ¶¶ 425-27.

AZ rejects these allegations summarily, but when coupled with other detailed allegations in the TAC, they provide exactly the sort of reliable indicia that, under *Foglia*, support a strong inference that the company's false and misleading promotion of Crestor induced prescriptions and caused false claims to be submitted and paid.

B. Whether an Off-Label Use is Medically Accepted (and Thus Reimbursable) Cannot be Determined at the Motion to Dismiss Stage

AZ argues that claims based on its promotion of Crestor for regression of atherosclerosis should be dismissed because such use is "medically accepted" and thus reimbursable by Government Programs. The argument is premature, but it also is flawed.

First, whether off-label uses are "medically accepted" based on compendia evidence (Mem. 7-8, 16) cannot be determined on a motion to dismiss because the Court's "job at this stage is not to test the sufficiency of the evidence underlying [the relator]'s allegations or to resolve factual disputes about the meaning of that evidence." *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *6 (C.D. Cal. July 10, 2014). Recently, Judge O'Neill reached a similar conclusion, declining to resolve on a motion to dismiss whether a drug was federally reimbursable for off-label use based on compendia evidence because the relator had "made detailed factual allegations in his [operative] complaint that [the drug] was not reimbursable." *Cestra*, 2014 WL 3498761, at *9. Judge O'Neill explained:

> Whether or not any particular use is 'supported' by the compendia is a complex, case-by-case inquiry not susceptible to resolution on a motion to dismiss" and indeed "expert testimony is often necessary to discern whether a mention in a compendium in fact constitutes sufficient support[.]"

Id. (following and quoting *Celgene*, at *5). The *Celgene* and *Cephalon* cases are not outliers.[10]

Here, the TAC includes detailed allegations that regression is not a reimbursable use of Crestor because it is not FDA-approved and not supported by the compendia (TAC ¶¶ 283-335; *see* discussion *supra* pp. 6-7, 17); and AZ implicitly concedes that DrugDex support for its regression theory is not explicit (Mem. 16). The disagreement cannot be resolved at this stage.

II. Relators Allege with Plausibility and Particularity that AstraZeneca Used Illegal Kickbacks to Cause False Claims to be Submitted and Paid

The AKS prohibits any person from knowingly offering to pay any remuneration – "including any kickback, bribe, or rebate" – to another person to induce the "purchase[]," "order[], or "recommend[ation]" of any "item for which payment may be made in whole or in

[10] *See*, *e.g.*, *United States v. King-Vassel*, 728 F.3d 707, 717 (7th Cir. 2013) (reversing summary judgment due to district court error presuming relator would be unable to prove claims since he failed to name a compendia expert); *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d at 369 n.8 (finding that reference to compendia on a motion to dismiss did not "resolve as a matter of law (or fact) whether [a drug] was marketed for medically unnecessary uses"); *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:11-00962, 2012 WL 8020674, at *7 (N.D. Ga. Aug. 29, 2012) ("Defendants' DRUGDEX evidence is not appropriate for consideration on a motion to dismiss under Rule 12(b)(6)"); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) ("preliminary record" on a motion to dismiss "is insufficient to determine whether the citations included in DRUGDEX . . . can be read to 'support' [a drug's] off-label use"). The United States submitted a Statement of Interest in *Celgene*, explaining:

> Evaluation of whether a compendium citation supports use of a drug for a particular indication involves a factual inquiry that should not be resolved at the motion to dismiss stage. Specifically, resolution of the question whether a particular use which a manufacturer is promoting is "supported by" a compendium citation depends on the exact use being promoted, the content of the compendium citation with respect to that exact use, and the scope and outcome of the studies as described in the compendium. Moreover, some studies which a compendium cites may well indicate that a particular off-label use has shown little to no efficacy in treating a medical condition or presents serious safety concerns for a particular patient population. . . . This Court should find that the factual record at the motion to dismiss stage is insufficient to make such a determination.

Celgene, 2014 WL 3605896, Dept. of Justice Statement of Interest 6-7, attached hereto as Exhibit A.

part under a Federal health care program." 42 U.S.C. § 1320a-7b(b). Claims for government reimbursement resulting from an AKS violation are "false" under the FCA. *Id*. § 1320a-7b(g).

AZ asserts that Relators' kickback allegations should be dismissed because they are not sufficiently specific, and because they describe actions that are supposedly consistent with lawful conduct. Mem. 17-20. This argument, too, must fail, for it ignores many allegations that describe how AZ's unlawful conduct ran afoul of the AKS and, in turn, the FCA.[11] For example:

- The TAC explains how AZ used financial payments to induce or reward speakers to present false and misleading information about unapproved and unproven uses of Crestor to their peers, the purpose and effect of which were to induce prescriptions and cause claims to be submitted. *See* TAC ¶¶ 439-56, 503-11.
- The TAC explains how AZ used financial payments to induce or reward healthcare professionals to direct deceptive CME courses in order to induce prescriptions and cause claims to be submitted. *See* TAC ¶¶ 457-77.
- The TAC explains how AZ used bogus advisory board compensation to induce prescriptions of Crestor for unapproved and unproven (and thus misleading) uses. *See* TAC ¶¶ 478-84.
- The TAC explains how AZ used kickbacks to induce NCEP ATP III Guidelines authors to support AZ's false and misleading superiority and safety messages. *See* TAC ¶¶ 485-95.

While it is not unlawful to compensate speakers and consultants for their time, it is illegal to pay them to induce prescriptions and claims through false and misleading information[12]; yet,

[11] Compliance with the AKS is a material condition of payment under federal health programs such as Medicare, and false certification of compliance is actionable under the FCA. *See Wilkins*, 659 F.3d at 312-13.

[12] *See*, *e.g.*, OIG Compliance Guidance for Pharm. Mfrs., 68 Fed. Reg. 23731, 23735 (May 5, 2003) ("[T]o the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.").

that is precisely what the TAC alleges – identifying specific recipients of AZ's kickbacks and describing the details of their activities. *See*, *e.g.*, TAC ¶¶ 446-54 (speakers), ¶ 467 (CME programs), ¶¶ 493-95 (NCEP ATP III authors). The TAC then explains – with reference to specific beneficiaries of AZ's improper largesse – that the kickback scheme did, in fact, induce the writing of prescriptions and the submission of claims. *Id*. ¶¶ 499-500, 504-09. Thus, AZ cannot credibly argue to dismiss the AKS claims without ignoring the language of the TAC.

III. Relators' Claims Based on Pre-2007 Conduct are not Time-Barred Because the TAC Either Repeats Factual Averments Contained in the SAC or the Averments Relate Back

AZ's attempt to avoid liability for pre-2007 violations should be rejected because the TAC describes pre-2007 conduct that was alleged in the SAC, and the averments of the TAC relate back to 2003.

A pleading amendment relates back to an original pleading when "the claim . . . asserted in the amended pleading arose out of the conduct, transaction or occurrence set forth or attempted to be set forth in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). In applying this standard, the Court considers "whether the party asserting the statute of limitations defense has been placed on notice that he could be called to answer" for the amended pleading's allegations. *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 516 (6th Cir. 2007) (citing *Santamarina v. Sears*, 466 F.3d 570, 573 (7th Cir. 2006)). The relation back rule should be interpreted with "liberality rather than technicality." *See Bledsoe*, 501 F.3d at 516.[13] Thus, the Court should hold that the claims set forth in the TAC arise out of the same transaction or occurrence as those set forth in the SAC if AZ can be said to have been on notice of, alerted to, or not surprised by the amplification of claims.

[13] The Third Circuit's application of this rule is consistent with the law outlined *supra*. *See*, *e.g.*, *Glover v. F.D.I.C.*, 698 F.3d 139, 146 (3d Cir. 2012); *Bensel v. Allied Pilots Ass'n*, 387 F.3d 298, 310 (3d Cir. 2004).

AZ argues that the TAC attempts to expand by four years the time period implicated by this suit. Mem. 20.[14] Not so. Attached as Exhibit B is a chart that compares the allegations of the TAC against those of the SAC. It identifies the TAC's material allegations concerning AZ's pre-2007 conduct, and it shows – with citation – whether each allegation is simply repeated from the SAC, or whether it relates back to the SAC. This chart confirms that AZ previously was on notice of all the claims stated in the TAC. In most instances, the TAC's pre-2007 allegations simply provide more detail for allegations that were previously pled – detail that AZ's earlier motion to dismiss the SAC had demanded. Accordingly, AZ's request that the Court dismiss claims based on pre-2007 conduct should be rejected.

IV. Relators Have Pled Valid State Law Claims for Relief

A. The TAC Sufficiently Alleges Claims Under the State Analogues to the FCA

Relators' state law claims satisfy minimum pleading requirements for the same reasons discussed *supra*; thus the Court should exercise pendent jurisdiction over them.

Acknowledging that courts construe state *qui tam* statutes consistently with the FCA, AZ urges the Court to decline to exercise supplemental jurisdiction over Relators' state claims based on an assumption that Relators' federal claims are deficient. Mem. 21-22. AZ cites the "balance of factors" to be considered in arriving at that conclusion (*i.e.*, efficiency, convenience, fairness and comity), but makes no attempt to examine those factors, let alone demonstrate how they would not be served by adjudicating pendant state law claims in this Court. *See id.; see also*

[14] The two cases cited by AZ are inapposite. In *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys.*, 409 F. Supp. 2d 43, 51-53 (D. Mass. 2006), the allegations of the original complaint were insufficient to trigger relation back because they were filed in the wrong venue and improperly alleged "on information and belief." Here, in contrast, the SAC was not pled on "information and belief." And, in *Reyes v. United States*, No. 04-1952, 2006 U.S. Dist. LEXIS 94291, *15-19 (D.N.J. Dec. 28, 2006), the amendment involved wholly different events in a different time period, and thus, were different "in time and type." Here, in contrast, the common core of operative facts alleged in the SAC and the TAC are the same.

United States ex rel. Digital Healthcare, Inc. v. Affiliated Computer Servs., Inc., 778 F. Supp. 2d 37, 55 (D.D.C. 2011) (citations omitted). Instead, AZ implies that the alternative – more than twenty separate trials in more than twenty separate state courts – somehow would be more efficient. This strains credulity. Plainly, a single trial in this forum would be the most fair and efficient result for all involved, including the judiciary.

B. The Delaware and New Mexico Claims Survive Without State Intervention

AZ argues separately to dismiss Relators' Delaware claim because the Delaware Attorney General has not issued a "written determination" that there is "substantial evidence" of a violation. Mem. 22. AZ concedes, however, that the law upon which it relies for that argument was eliminated from the Delaware False Claims Act in 2009, *i.e.*, before Relators filed the SAC. Mem. 22 n.7. Significantly, Relators only seek to apply the Delaware statute for conduct that occurred after July 16, 2009.[15]

AZ makes the same argument to dismiss Relators' New Mexico claim, arguing that the statute authorizes Relators to proceed with a declined case only if the state determines there is "substantial evidence" the statute has been violated. *See* N.M. Stat. § 27-14-7(E)(2). This argument is premature, at best. *See United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520-21 (S.D. Tex. 2011), *order vacated in non-relevant part on reconsideration*, No. C.A. No. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) (dismissal based on lack of determination by state is not appropriate ground for dismissal under Rule 12(b)(6)).

C. Relators Do Not Seek Retroactive Application of State Claims

AstraZeneca argues that claims based on conduct that occurred prior to the effective date of certain state *qui tam* statutes should be dismissed because the state laws are not retroactive.

[15] Relators concede that their Maryland claim should be dismissed (without prejudice) because the state has declined to intervene. *See* Md. Code Ann., Health-Gen § 2-604(A)(7).

Mem. 23-24. The TAC does not seek to apply any statute to conduct that occurred prior to its effective date, however, thereby rendering AZ's argument moot as to all states except New York.

The New York False Claims Act provides that it "shall apply to claims filed or presented before, on or after April 1, 2007." N.Y. STATE FIN. LAW § 187. This forecloses AZ's argument that the law is not retroactive. *See United States ex rel. Bilotta v. Novartis Pharms. Corp.*, 50 F. Supp. 3d 494, 547 (S.D.N.Y. 2014) (concluding the NYFCA does not bar claims based on conduct occurring before April 1, 2007).

D. Relators Do Not Lack Standing under the New Mexico Statute

AstraZeneca argues that Relators' New Mexico claim should be dismissed because only "affected persons" have standing to pursue private civil actions under the New Mexico FCA. Mem. 24-25. AZ cites no New Mexico authority for its restrictive interpretation of the statute, yet insists that "federal courts have unambiguously found that residents of states other than New Mexico are not 'affected person[s].'" Mem. 25 (citing *Solvay*, 823 F. Supp. 2d at 520-21, as the lone authority for the proposition that only New Mexico residents have standing as "affected persons"). To the contrary, at least two federal courts have expressly rejected AZ's (and *Solvay*'s) narrow interpretation.[16] Accordingly, Relators have standing to pursue their claim.

V. Relator Lorden's Claims are not Barred by the First-to-File Rule

AZ's argument that the Court lacks subject-matter jurisdiction over Mr. Lorden's claims ignores the plain language of the FCA and, regardless, its argument was recently gutted by the

[16] *See Cestra*, 2015 U.S. Dist. LEXIS 71505, at *42-43 (noting "there is no apparent natural connection between whether a person is 'affected' by conduct under the New Mexico FCA and New Mexico residency"); *see also Celgene*, 2014 WL 3605896, at *41-42 (refusing to adopt a more limited reading of New Mexico's use of "affected person").

Supreme Court.[17] When an individual files an FCA case, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). Based on a plain reading of the statute, this so-called "first-to-file" rule precludes claims that are brought in a *separate* action, and claims that are brought through *intervention* under Rule 24. *See*, *e.g.*, *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1017 (10th Cir. 1994); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2014 U.S. Dist. LEXIS 144056, at *10 (E.D. Pa. 2014) ("I have no reason to doubt that Congress anticipated that the plain meaning of 'intervene,' when used in the context of a procedural bar to filing FCA actions, would be understood by the courts consistent with the Federal Rules of Civil Procedure."); *Educ. Mgmt. Corp.*, 871 F. Supp. 2d at 459 (declining to dismiss amendment to add relator since "[t]he plain text of § 3730(b)(5) does not apply to the unique procedural status of this case because [the new relator] is not 'intervening' or bringing a 'related action.'").

Here, Mr. Lorden did not bring his claims in a separate action, nor did he intervene pursuant to Rule 24. Instead, his claims were added to the original *Foote* action through a voluntary amendment pursuant to Rule 15; thus, they are not barred by the first-to-file rule.

In this regard, AZs' reliance on *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227 (3d Cir. 1998) (Mem. 25), is misplaced. *LaCorte* involved six relators who joined in one FCA action, and three additional relators joined in a *separate*, later-filed FCA action. *Id.* at 230-31. The Third Circuit held that the first-to-file rule barred only the latter three relators' claims because similar claims had been brought in three separate, earlier-filed actions. *Id.* at 238. That is not the case here. *Cf. Educ. Mgmt. Corp.*, 871 F. Supp. 2d

[17] Moreover, the D.C. Circuit held this week in *Heath*, *supra*, that the first-to-file rule is not jurisdictional. *Heath*, *supra*, 2015 U.S. App. LEXIS 10547, at *13-14.

at 460 (stating that the Third Circuit's application of the first-to-file bar in *LaCorte* was limited to "case[s] [that] did not involve an additional plaintiff added to the same lawsuit").[18]

Policy considerations likewise support the view that the first-to-file rule only precludes claims that are brought in a separate action or through intervention. Section 3730(b)(5) was enacted, in part, to protect first-filed relators against opportunistic, later-filing claimants "chas[ing] after generous cash bounties." *LaCorte*, 149 F.3d at 233. Such concerns have merit in the context of separately filed actions or a Rule 24 intervention, but not where, as here, the relators have consented to join together in an amended complaint and share in any proceeds. *Cf. Boise*, 2014 U.S. Dist. LEXIS 144056, at *9 (stating that "policy considerations underlying th[e] provision" convinced the court to allow the addition of relators by amended complaint). Mr. Lorden first asserted his claims through an amendment to the original *Foote* complaint – not through a separate action or intervention; thus, they are not barred by the first-to-file rule.

AZ also argues that Mr. Lorden's claims are barred by the *De Souza* action, even though that action was dismissed *before* Foote and Lorden filed their TAC. Mem. 27. AZ is incorrect. On May 26, 2015, a unanimous Supreme Court confirmed that the first-to-file rule does *not* bar a later-filed related action once the earlier-filed action has been dismissed – even if the earlier action had been pending when the second case was filed. *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1979, (2015) (construing FCA's use of the term "pending" to mean that the first-to-file bar keeps new claims out of court only until related

[18] The two New Jersey cases cited by AZ (Mem. 25) are similarly unpersuasive because they ignore the plain language of the statute, which refers only to claims brought separately or through intervention. *Cf. Boise*, 2014 U.S. Dist. LEXIS 144056, at *11 (stating that "Third Circuit case law persuade[d] [the court] that the first-to-file rule does not apply to the voluntary addition of relators by amended complaint in a pending action where relators have entered into a private agreement regarding the division of potential proceeds from the action.").

claims have been dismissed). Thus, Mr. Lorden's claims are not barred by *De Souza* because *De Souza* was no longer pending when Foote and Lorden filed the operative TAC. Mem. 27 n.14.[19]

VI. To the Extent Any Claims are Dismissed, Such Dismissal Should be Without Prejudice, and Relators Should be Permitted to Cure any Deficiency with an Amended Pleading

Should the Court dismiss one or more claims, such dismissal should be without prejudice. Generally, plaintiffs are allowed at least one opportunity to cure pleading defects by "providing a better factual account of the alleged claim." *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 517 (3d Cir. 2007); *see Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002); *Shane v. Fauver*, 213 F.3d 113, 116-17 (3d Cir. 2000); *Blunt v. Lower Merion Sch. Dist.*, 559 F. Supp. 2d 548, 577 (E.D. Pa. 2008), *aff'd*, 767 F.3d 247 (3d Cir. 2014).

The suggestion that Relators should be denied an opportunity to cure any deficiency because they already have had time to do so is misleading. The original complaint was filed on February 5, 2010, but the case remained *under seal* (by statute, and at the request of the United States) until October 31, 2013 [D.I. 1, 2 & 50]. When the case was unsealed, AZ sought and received two extensions of time to respond. [D.I. 53 & 54] After AZ filed its initial response on January 5, 2015 [D.I. 63], Relators promptly filed their TAC on March 5, 2015 [D.I. 68], as permitted by Rule 15(a)(1)(B).

Thus, the passage of time is not attributable to any action or inaction by Relators, nor did they have notice during the bulk of that period of any pleading deficiencies that might merit correction. If the Court were to grant AZ's motion, either in whole or in part, that would be the *first time* that the Court will have passed on the allegations, and the first opportunity the Relators

[19] Application of the first-to-file rule is determined by the last-filed complaint, and not the original complaint or prior amendments. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473-74 (2007) ("when a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction.").

would have to cure any deficiencies the Court may identify. *Cf. Cureton v. NCAA*, 252 F.3d 267, 273 (3rd Cir. 2001) (stating that the "mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay," and that delay will only become "undue" if it places an "unwarranted burden on the court" or will "place an unfair burden on the opposing party"); *Adams v. Gould, Inc.*, 739 F.2d 858, 868 (3d Cir. 1984) (finding that a motion to amend a complaint should not be denied based solely on the passage of time).[20]

That Relators' employment by AZ ended five or more years ago is irrelevant. Although they endeavored to satisfy specificity requirements in their operative pleading, the conclusion of Relators' employment does not mean necessarily that, if required by the Court, they could not supplement their allegations in order to provide a better factual account.

And finally, though AZ would incur additional costs to respond to a further amended complaint, that alone does not necessitate a dismissal with prejudice. The lone case relied upon by AZ to support this proposition, *Cureton*, 252 F.3d at 273-74, involved an attempt to amend a complaint by adding new (and previously known) claims *after* summary judgment had been granted for the defendant, which would have required additional discovery. The instant case is materially distinct. Relators have had no prior opportunity to correct any pleading deficiencies identified by the Court; thus, to the extent any claim is dismissed, such dismissal should be without prejudice and with leave to amend to cure any deficiency identified by the Court.

CONCLUSION

For the foregoing reasons, AZ's Motion to Dismiss the TAC should be denied.

[20] The instant case is materially different than *United States ex rel. Garcia v. Novartis AG*, No. 06-10465-WGY, 2015 U.S. Dist. LEXIS 32771, at *21 (D. Mass. Mar. 17, 2015) (Mem. 27). That case was dismissed with prejudice because one relator waited a year before complying with the court's explicit order to file an amended complaint, and the other relator squandered numerous opportunities over a period of six years to include certain information in the complaint, despite having such information from the outset. *Id.*

Respectfully submitted,

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